Europäisches Patentamt

European Patent Office

Office européen des brevets



(11) EP 0 982 044 A2

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication: 01.03.2000 Bulletin 2000/09

(51) Int CL7: **A61M 16/01**, A61M 16/08,

A61M 16/00

(21) Application number: 99306804.8

(22) Date of filing: 26.08.1999

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU

MC NL PT SE

Designated Extension States:

Designated Extension States: AL LT LV MK RO SI

(30) Priority: 26.08.1998 US 140706

(71) Applicant: INSTRUMENTARIUM CORPORATION SF-00510 Helsinki (FI)

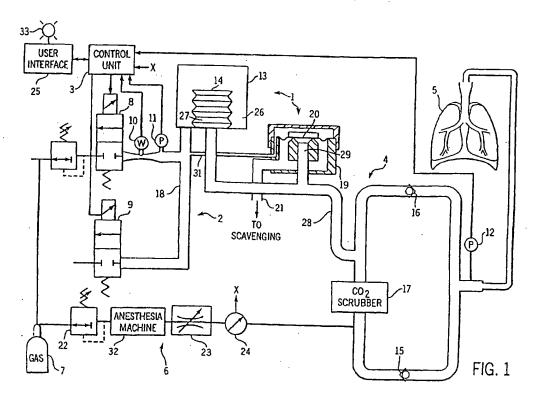
(72) Inventor: Heinonen, Erkki 00750 Helsinki (FI)

(74) Representative: Charlton, Peter John Elkington and Fife Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)

(54) Method and apparatus for detecting an empty gas compartment in a patient ventilator

(57) An apparatus/method for detecting an empty breathing gas compartment condition in a bellows ventilator for a patient. The apparatus includes a first sensor for measuring, during inspiration, the incoming flow of gas into a driving gas compartment located in the bellows container. The second sensor measures the pressure in the driving gas compartment. During the inspiration cycle, measurements taken by the first and sec-

ond sensors are signaled to a control unit and used to determine a $\Delta V\!/\Delta p$ compliance value. The compliance value will be large if the bellows is movable, i.e. not in the empty breathing compartment gas condition. The compliance value is small if the empty breathing gas compartment condition exists. The compliance value, so determined, is compared with a reference compliance value in the control unit to detect the empty breathing gas compartment condition.



EP 0 982 044 A2

Drinted by January 7500 - Dr Did in

10

tered in anesthesia practice.

[0009] The technique of the present invention employs use of information concerning the driving gas flow, the driving gas pressure within the container, and the volume of the container. When the barrier is freely moveable within the container, upon the supply of driving gas, the driving gas pressure increase within the container represents the joint compliance of all of the container, the breathing circuit, and the patient's lungs. This joint compliance, $\Delta V/\Delta P$, is large, typically over 30 ml/cmH₂O, and in any case over 6 ml/cmH₂O.

[0010] When the movement of the barrier is stopped due to an empty breathing gas compartment, the driving gas pressure rise in the container will depend only on the container compliance and the volume of driving gas delivered into the container. As the container is rigid, the compliance is determined by gas compressibility, thus by container volume. The container volume in a ventilator is usually a constant which does not vary during the course of treatment or the life cycle of the device. Thus, in an empty breathing gas compartment condition, the compliance measured in the ventilator is essentially constant.

[0011] Ordinarily the volume of the container plus associated gas flow circuitry is about two liters. From the general ideal gas equation, pV=nRT, for a constant volume V and constant temperature T, pressure is proportional to the amount of gas n, which in the ideal gas equation is in moles. It follows that adding a quantity of gas to a given volume will increase the pressure. Thus, adding e.g. two ml of gas to a 2000 ml quantity of gas present in the volume of the container and gas flow circuitry at 1000 mbar (ambient pressure) will give a pressure in the container of 1001 mbar or 1001 cm H₂O. The compliance ΔV/Δp of the container is 2 ml/cmH₂O and is the compliance exhibited when movement of the barrier is stopped due to an empty breathing gas compartment.

[0012] For recognition of the empty breathing gas compartment condition in a patient ventilator, the magnitude of this quantity as compared to the smallest values encountered in normal operation is readily apparent. Further, a recognition of the empty breathing gas compartment condition using the container compliance quantity encountered in that condition is independent of the make and size of the breathing circuit and parameters affecting pressure within the circuit.

[0013] The constancy of the container compliance whenever the empty breathing gas compartment condition is encountered is an advantage in the detection technique of the present invention. A further advantage is that this compliance value, in normally encountered operation, can be dedicated to detecting the empty breathing gas compartment condition, although a slight overlap between the empty and non-empty bellows condition compliance values may exist.

[0014] It is possible, though highly unlikely, for the technique of the present invention to erroneously iden-

tify an empty bellows condition. This may arise from the supply of fresh gas to the breathing circuit.

[0015] Compliance as seen by the ventilator is the integrated driving gas flow divided by the corresponding change in the pressure. This compliance value is subject to alteration due to the unknown fresh gas flow supply to the breathing circuit through the fresh gas supply line at the same time the driving gas is being supplied to the bellows container. The supply of fresh gas will increase the detected pressure of the driving gas and thus reduce the measured compliance value. An erroneous empty bellows detection will result when the fresh gas flow supplies the breathing circuit an amount of gas that causes a compliance measurement error that corresponds to the difference between the true compliance value and the empty breathing gas compartment compliance value.

[0016] The overall compliance is, as noted, 6 ml/cmH₂O at the minimum The empty breathing gas compartment compliance value measured by the ventilator is 2 ml/cmH₂O. Thus the minimum difference between these two is 4 ml/cmH₂O, The compliance C₁ exhibited in the patient ventilator is

$$C_1 = \Delta V_1 / \Delta p \tag{1}$$

where ΔV_1 is the volume of driving gas and Δp is the pressure increment detected in the ventilator. The compliance C_2 arising from the supply of fresh gas is

$$C_2 = \Delta V_2 / \Delta p \tag{2}$$

where ΔV_2 is the volume delivered by the fresh gas unit at the same time the ventilator employs the volume ΔV_1 . [0017] Since gas volume is the product of gas flow and time and the same time period is employed in both flow quantities F_{dr} (the driving gas flow) and F_{fg} (the fresh gas flow), these quantities multiplied by time t can be substituted for the respective volume quantities ΔV_1 and ΔV_2 .

[0018] Equation (2) can be transposed to

$$F_{fg} = C_2 \times \Delta p/t \tag{3}$$

[0019] Equation (1) can be transposed to

$$\Delta p = F_{dr} \times t/C_1 \tag{4}$$

[0020] Substituting equation (4) into equation (3) provides

$$F_{fg} = (C_2/C_1)F_{dr}$$
 (5)

55

[0032] Ventilator tube 28 also has a limb 29 connected to an exhaust valve 19. The pressure in breathing gas compartment 27 and breathing circuit 4 is thus provided to one side of exhaust valve membrane 20 in valve 19. A gas pressure equal to the pressure in driving gas compartment 26 is transmitted to the exhaust valve 19 through a tube 31 connected between driving gas conduit 18 and exhaust valve 19 and is applied to the other side of exhaust valve membrane 20. During inspiration, this latter pressure keeps exhaust valve 19 closed as the pressure within the breathing circuit 4 increases.

[0033] During the expiration cycle, the ventilator control unit 3 closes the inspiration valve 8 and opens the expiration valve 9. In doing so, the pressure is relieved from the driving gas compartment 26 of container 13. The elasticity of the patient's lungs 5 pushes the breathing gas out of the lungs 5 through the breathing circuit 4 in a flow direction defined by the one-way valves 15 and 16 back to breathing gas compartment 27 of container 13 to fill the breathing gas compartment. As the breathing gas compartment 27 is being refilled with the exhaled breathing gas, the pressure within the breathing circuit 4 will rise, forcing exhaust valve membrane 20 in exhaust valve 19 to open the valve. Any excess gas pressure over the pressure within driving gas conduit 18 is relieved through exhaust valve 19 into a gas scavenging outlet 21. The amount of gas relieved through exhaustivalve 19 to scavenging outlet 21 depends on the amount of the fresh gas delivered into the breathing circuit 4 from the fresh gas delivery unit 6. The smaller the flow of incoming fresh gas is, the smaller the exhausted gas volume will be, and vice versa.

[0034] The delivery of fresh gas to breathing circuit 4 is controlled by adjusting the fresh gas flow using a pressure regulator 22 and a flow regulator 23. The actual volume of fresh gas delivered is monitored by a flow sensor 24. Flow sensor 24 may be connected to ventilator control unit 3, as shown by the connection X-X, to compensate the driving gas volume in accordance with the amount of fresh gas flow to improve the control of patient ventilation.

[0035] CO₂ scrubber 17 removes carbon dioxide from the exhaled breathing gases of the patient.

[0036] From the above operational description, it is apparent that the ventilator control unit 3 receives from the system all the necessary data from the system to determine an actual compliance value for the apparatus. Flow sensor 10 senses the driving gas flow delivered to the container 13. Integrating this gas flow over the time the flow was supplied gives the total volume of gas supplied to the driving gas conduit 18. Pressure sensor 11 monitors the corresponding pressure of the driving gas in container 13. The compliance is then calculated using these values. This calculated actual compliance value can then be compared with a reference compliance value that is representative of the empty breathing gas compartment condition to determine whether such a condition exists. When this condition is encountered, the

control unit 3 may cease the driving gas delivery to container 13 to avoid damage by over-pressurization. Also, control unit 3 may notify the user through the user interface 25 and an alarm 33 of the empty breathing gas container condition and that corrective action is immediately required. The corrective action to be taken may include an adjustment of the fresh gas flow or the sealing of any possible leaks present within the breathing circuit 4. Such steps allow breathing gas compartment 27 of container 13 to fill with gas.

[0037] Although the detailed description illustrates the invention in connection to a ventilator system where a rising bellows represents the moving, barrier 14 separating the driving gas compartment 26 and the breathing gas compartment 27, it is obvious to one skilled in the art that the present invention could also be applied in connection with any comparable ventilation system. Some comparable ventilation systems are, e.g. those in which a hanging bellows or a bag is utilized as the moving barrier 14, both alternatives representing, in terms of the present invention, equivalent ventilation systems. [0038] Also, while flow sensor 10 and pressure sensor 11 are shown and described in connection with driving gas conduit 18, it will be appreciated that they may be located elsewhere in the apparatus, for example in association with container 13.

[0039] Various other alternatives and embodiments are contemplated as being within the scope of the following claims particularly pointing out and distinctly claiming the subject matter regarded as the invention.

Claims

- 1. A method for detecting an empty breathing gas compartment condition in apparatus for ventilating a patient's lungs with breathing gas, the breathing gas compartment being located in a container and separated from a driving gas compartment by a movable barrier, the driving gas compartment being pressurizable by a driving gas to compress the breathing gas compartment to provide breathing gases to the patient, the breathing gas compartment being expandable by exhaled gases of the patient, said method comprising the steps of:
 - supplying driving gas to the driving gas compartment of the container;
 - measuring a volumetric property of one of the gases in the container;
 - measuring a gas pressure property indicative of that existing in the container resulting from the supply of driving gas;
 - determining a compliance property from the volumetric and pressure properties so measured; and
 - ascertaining from the compliance property whether an empty breathing gas compartment

5

10

30

35

40

ascertaining that an empty breathing gas compartment condition exists in the apparatus when the determined compliance property bears a predetermined relationship to the reference value.

17. An apparatus for detecting an empty breathing gas compartment condition in apparatus for ventilating a patient's lungs with breathing gas, the breathing gas compartment being located in a container and separated from a driving gas compartment by a movable barrier, the driving gas compartment being pressurizable by a driving gas from a source of driving gas to compress the breathing gas compartment to provide breathing gases to the patient, the breathing gas compartment being expandable by exhaled gases of the patient, said apparatus comprising:

a first sensor for measuring a volumetric property of one of the gases in the container, a second sensor for measuring a pressure property indicative of that existing as a result of the supply of driving gas; and means coupled to said first and second sensors for determining a compliance property from the volumetric and pressure properties so measured and for ascertaining from the compliance property whether an empty breathing gas compartment condition exists in the apparatus.

- 18. The apparatus of claim 17 wherein said first sensor is further defined as measuring a volumetric property of the driving gas supplied to the driving gas compartment of the container.
- 19. The apparatus of claim 17 wherein said second sensor is further defined as measuring a gas pressure property existing in the container.
- 20. The apparatus of claim 18 wherein said second sensor is further defined as measuring a pressure property of the driving gas.
- 21. The apparatus of claim 18 wherein said first sensor is further defined as measuring the supply of an incremental volume of driving gas to the driving gas compartment, and wherein said second sensor is further defined as measuring an incremental change in the pressure of the driving gas compartment as a result of the supply of the driving gas volume, and wherein said determining and ascertaining means is further defined as means for determining the compliance property from the incremental volume supply and pressure change.
- 22. The apparatus of claim 21 wherein said determining and ascertaining means is further defined as deter-

mining the compliance property from the relationship between the incremental gas supply volume and the corresponding change in driving gas compartment pressure.

- 23. The apparatus of claim 21 wherein said first sensor is further defined as integrating the flow of driving gas over a period of time and wherein said second sensor is further defined as integrating the change in pressure over the same period of time.
- 24. The apparatus of claim 17 wherein said first sensor is further defined as obtaining a derivative of volume with respect to time and said second sensor is further defined as obtaining a derivative of pressure with respect to time.
- 25. The apparatus of claim 17 wherein said determining and ascertaining means is further defined as means for comparing the determined compliance property to a reference value.
- 26. The apparatus of claim 25 wherein said determining and ascertaining means is further defined as means for establishing a compliance reference value and for ascertaining that an empty breathing gas compartment condition exists in the apparatus when the determined compliance property bears a predetermined relationship to the reference value.
- 27. The apparatus of claim 18 wherein the driving gas compartment is supplied with driving gas through a conduit from the driving gas source and wherein said first sensor is couplable to the conduit.
- 28. The apparatus of claim 17 wherein the breathing gas compartment is in fluid communication with a breathing circuit for the patient, the breathing circuit receiving a flow of fresh gas and wherein said apparatus is further defined as including means for suppressing an indication of the empty breathing gas condition responsive to predetermined relative magnitudes of the driving gas flow and fresh gas flow.
- 29. The apparatus of claim 17 further including means coupled to said determining and ascertaining means for providing a perceptible indication of an empty breathing gas compartment condition.
- 30. The apparatus of claim 17 further defined as apparatus for detecting an empty breathing gas compartment in ventilating apparatus in which the movable barrier between the driving gas compartment and breathing gas compartment is a collapsible bellows.
- The apparatus of claim 18 further defined as apparatus for detecting an empty breathing gas compart-

55

